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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,073	12/09/2003	Sujay Singh	IMG-00112.P.2-US	3772

24232 7590 04/11/2006

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,073	SINGH ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14,15 and 17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11,14,15 and 17-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 12, 13, 16 and 17 have been canceled. Claims 1-11, 14, 15 and 18-22 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 6 and 11, drawn to a transgenic bird having a knockout of an endogenous immunoglobulin gene, classified in class 800, subclass 19.

II. Claims 1-11, drawn to transgenic bird having a knockout of an encoding immunoglobulin gene and an insertion of an exogenous immunoglobulin gene, classified in class 800, subclass 19.

III. Claims 15, 19 and 22, drawn to an antibody, classified in various classes and subclasses.

IV. Claims 14 and 18, drawn to making a chimeric antibody using a transgenic bird immunized with an antigen and isolating the antibody from B-cells of the bird, classified in class 800, subclass 4.

V. Claims 20 and 21, drawn to transfecting cells with DNA encoding an antibody, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the transgenic bird lacking an immunoglobulin gene can be used to study the role of the gene on the immune system of birds in vivo while the transgenic bird lacking an endogenous immunoglobulin gene and expressing an exogenous immunoglobulin gene can be used to make chimeric

antibodies. The protocols and reagents for knocking out a gene are materially distinct and separate than those required to insert an exogenous gene. The knockout bird does not require the bird having a knockout and an exogenous gene because the knockout can be performed by itself. The bird having a knockout and an exogenous gene does not require the knockout because both the knockout and insertion can be performed at the same time.

Groups I and III are patentably distinct because the knockouts can be used to study the role of the gene on the immune system of birds in vivo while the antibody can be used to isolate protein. The protocols and reagents for transgenics and antibodies are materially distinct and separate. The birds do not require the antibodies and the antibodies do not require the birds.

Groups I and IV are patentably distinct because the transgenic bird lacking an immunoglobulin gene can be used to study the role of the gene on the immune system of birds in vivo while the method of making an antibody in Group IV is used to make chimeric antibodies. The protocols and reagents required for making a transgenic bird are materially distinct and separate than those required for using a bird to isolate antibodies. The knockout does not require the method of isolating antibodies and the method of isolating the antibodies does not require the knockout.

Groups I and V are patentably distinct because the knockouts can be used to study the role of the gene on the immune system of birds in vivo while transfecting cells with DNA encoding an antibody can be used to isolate antibodies. The protocols and reagents for making transgenics and for transfecting cells are materially distinct and

separate. Transgenics do not require the particulars of the method of transfecting cells for patentability and the method of transfecting cells can be used for purposes other than making transgenics, i.e. isolating antibodies in vitro.

Groups II and III are patentably distinct because the knockout having an exogenous immunoglobulin gene can be used to isolate chimeric antibodies while the antibody can be used to humanize chicken antibodies. The protocols and reagents for transgenics and antibodies are materially distinct and separate. The birds do not require the antibodies and the antibodies do not require the birds.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP j 806.05(h)). In the instant case the method can be performed in a transgenic bird having an exogenous immunoglobulin gene without having a knockout. In addition, the method can be performed two materially distinct and separate ways, isolating the antibody from the serum or egg white of the bird or isolating the antibody from B-cells made by the bird.

Groups II and V are patentably distinct because the knockout having an exogenous immunoglobulin gene can be used to isolate chimeric antibodies in vivo while transfecting cells with DNA encoding an antibody can be used to isolate antibodies in vitro. The protocols and reagents for making transgenics and for transfecting cells are materially distinct and separate. Transgenics do not require the

particulars of the method of transfecting cells for patentability and the method of transfecting cells can be used for purposes other than making transgenics, i.e. isolating antibodies in vitro.

Inventions III and IV or V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP j 806.05(f)). In the instant case the method can be used to make various chimeric antibodies, each of which has a different structure and function. In addition, the antibodies can be made by isolating the antibody from the serum or egg white.

Inventions IV and V are patentably distinct because a "knockin" transgenic bird immunized with an antigen can be used to make human/bird chimeric antibodies while the method of transfecting cells with immunoglobulin DNA is limited to producing the immunoglobulin encoded by the DNA. The protocols and reagents for making antibodies using a transgenic chicken are materially distinct and separate than those required to make antibodies using transfected cells. The two groups are not disclosed as being used together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER